



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Inert (other) Ingredients in Pesticide Products

Pesticide Fragrance Notification Pilot Program

April 17, 2007

Attention: Persons Responsible for Federal Registration of Pesticide Products

Subject: Availability of Fragrance Notification Pilot Program for Formulation Changes Involving Fragrances in Currently Registered Products

I. Overview.

EPA's Office of Pesticide Programs (OPP) is implementing a Pilot Notification Program for registrants seeking to add or modify fragrances in currently registered pesticide products. OPP is initiating the Fragrance Notification Pilot Program as a process improvement to streamline the current process used to amend registrations when fragrance ingredients are added, removed, or modified. The pilot is intended to give registrants and OPP experience in a potential future notification process for fragrance formulation changes. This will be a 120-day pilot program, which will begin on May 1, 2007, and end on August 31, 2007.

The Fragrance Materials Association (FMA) developed, on its own initiative, a list of more than 1500 fragrance component ingredients sorted by chemical names and CAS Registry Numbers. EPA is making this Fragrance Ingredient List (FIL) available to the public for use in the Pilot Notification Program. EPA is currently reviewing and validating the FIL fragrances and fragrance components for completeness and accuracy and is interested in receiving public comment on FMA's FIL. Once validated, the FIL could serve as a readily accessible resource for registrants seeking information on fragrance component ingredients cleared for use in pesticide products. FMA's FIL is available at:
www.epa.gov/opprd001/inerts/.

Upon satisfactory completion of the pilot program, EPA will consider adoption of a notification program for fragrance changes that involve only fragrance component ingredients on the validated FIL. EPA will update the FIL as fragrance component ingredients are either approved for use or removed from use in pesticide products.

II. Current Amendment Process.

Currently, registrants wishing to add or modify fragrances in registered products do so by amendment to the Confidential Statement of Formula (CSF). Often, the fragrance composition is known only to the fragrance supplier. The current amendment process requires that fragrance suppliers provide a confidential declaration of the fragrance ingredients under separate cover to the Agency. A finished fragrance normally includes complex mixtures of many fragrance ingredients. Each fragrance formula is separately reviewed by the Inert Ingredient Assessment Branch in OPP's Registration Division (RD). EPA is hoping the FIL will reduce the number of submissions that contain unapproved ingredients by assisting registrants and fragrance suppliers in identifying approved fragrance ingredients.

III. Eligibility for Participation in the Pilot Fragrance Notification Program.

Participation in the Pilot Fragrance Notification Program is limited by the following:

- 1) The proposed fragrance addition/change must be the only change to the CSF being sought in the particular pilot program submission. [Proposed changes to fragrance descriptors (e.g., "New Bouquet Fresh") are not eligible for the pilot and must be submitted separately to OPP's Antimicrobial Division (AD).]
- 2) The concentration of the fragrance being added/changed must not exceed 1.0% (by weight) of the total pesticide product composition.
- 3) All fragrance component ingredients in the newly-proposed fragrance must be included on the FIL.
- 4) Individual fragrance component ingredients that would exceed 0.1% (by weight) of the total pesticide product composition must have existing approval for use as pesticide product inert ingredients.
- 5) Fragrance actions involving pesticide products that are insect repellents or baits are not eligible for the pilot program.

IV. Pilot Fragrance Notification Program.

EPA will employ the Pilot Fragrance Notification Program to ensure that a fragrance notification procedure can be responsibly implemented. During the pilot, the composition of each fragrance formula will be provided to OPP so that it can verify that the ingredients in the fragrance formula, in fact, are cleared for use and are on the FIL.

Registrants who choose to participate in the pilot program will be responsible for submitting the following:

- EPA Form 8570-1 (Application for Pesticide Registration/Amendment) identifying the submission as an addition of a fragrance eligible for the Pilot Fragrance Notification Program. The form is available at www.epa.gov/opprd001/forms.
- Revised Confidential Statement of Formula (CSF). The form is available at www.epa.gov/opprd001/forms.

- Fragrance Certification Letter (See attached). This letter is signed by the fragrance supplier and/or the antimicrobial pesticide registrant and must accompany the fragrance formula.
- Fragrance formula spreadsheet identifying each ingredient by CAS Reg. No. and chemical name (submitted by either the registrant or fragrance supplier in an Excel spreadsheet – see below).

Registrants will submit a new CSF reflecting the new or modified fragrance and form 8570-1 indicating [or stating] that the only proposed change to the revised CSF is a new or modified fragrance and that the new fragrance is eligible for the Fragrance Notification Pilot Program. In addition, the registrant will provide a copy of the Certification Form from the fragrance supplier that all of the fragrance ingredients are on the FIL.

For the fragrance formula, fragrance suppliers (or registrants on behalf of the supplier) are to submit the fragrance formula identifying each ingredient by CAS Reg. No. and chemical name. The fragrance formula spreadsheet is to be submitted to OPP in both paper and electronic versions (on a CD) using an Excel spreadsheet format, which is available at www.epa.gov/opprd001/inerts. Fragrance suppliers may submit the fragrance formula spreadsheet under separate cover to OPP. It is important that the fragrance supplier identify an individual with contact information to resolve questions regarding the submission. The Fragrance Certification Letter (see attached) must accompany the fragrance formula spreadsheet. This letter is signed by the fragrance supplier and/or the antimicrobial pesticide registrant.

Please follow the submission/mailling instructions in the next section.

OPP will perform its regular review of the proposed registration amendment. In addition, OPP will compare the submitted fragrance formula ingredients to the FIL to confirm that all of the new or modified fragrance ingredients are on the FIL. For the purpose of evaluating the pilot, OPP will maintain records of the comparisons and affirm to both the fragrance supplier and the registrant whether the comparison was successful. If OPP identifies any fragrance ingredients in the new or modified fragrance not on the FIL, the fragrance supplier and the registrant will be notified. Only those pesticide products for which all fragrance ingredients are currently cleared for use in pesticides and which are included on the FIL are eligible for this pilot.

V. Submission instructions.

When submitting the information identified above for this pilot, please follow the instructions for submitting various types of applications to OPP found in Pesticide Registration (PR) Notice 2006-1, April 12, 2006, entitled “New Instructions for Transmitting Information to the Office of Pesticide Programs”. www.epa.gov/PR_Notices/. Please send the submission to:

Submissions via the U.S. Postal Service: Address the submission using the official mailing address and mail codes below:

Document Processing Desk (AMEND -- Fragrance Pilot)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Submissions via Hand Delivery or Courier Delivery: Deliveries by you or a commercial courier should be directed to:

Document Processing Desk (AMEND -- Fragrance Pilot)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

VI. Submitting public comments on the FIL.

Please submit comments on the FIL to:

Pauline Wagner
Office of Pesticide Programs (7505P)
U. S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

VII. Contact Information.

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ATTACHMENT

Fragrance Certification Letter for the Fragrance Notification Pilot Program

(Product Name)
EPA Reg. No.

This certifies that all of the ingredients found in fragrance formula _____ to be used in EPA Reg. No. _____ are listed in the Fragrance Ingredient List (FIL) thus making this submission eligible for the Fragrance Notification Pilot Program. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this certification is not consistent with the terms of the Fragrance Notification Pilot Program and 40 CFR 152.46, this product may be in violation of FIFRA, and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

The fragrance formula in the Excel spreadsheet format is being submitted with this letter.

This letter is signed by the fragrance supplier and/or the antimicrobial pesticide registrant, as follows:

Signature, Fragrance Supplier
(Name, Fragrance Supplier, Address, Phone)

Date

AND/OR

Signature, Antimicrobial Pesticide Registrant
(Name, Antimicrobial Company)
(Registrant Name)
(Registrant Address)
(Registrant city, state, zip code)

Date